

NC 84,381
App. No.10/706,088

REMARKS

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The Office Action required a restriction between the following groups:

1. Claims 1- 17, drawn to methods of immunization against malarial disease comprising administering a priming immunization containing alphavirus replicons expressing a gene encoding malarial antigens, and a booster immunization containing the malarial antigens, classified in class 424, subclass 93.2.
2. Claims 18-26, drawn to immunogenic compositions comprising a first component containing alphavirus replicons expressing a gene encoding malarial antigens, and a second component containing the malarial antigens, classified in class 424, subclass 93.2.

Applicants elect Group I (Claims 1-17) with traverse.

There are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) the invention must be independent and (B) there must be a serious burden on the Examiner if restriction is required. Here the method claims of Group I and the composition claims of Group II are both relate to a single type of virus, alphavirus. Applicants note that the two Groups are also classified in the same class and subclass. Therefore, limited additional, if any, search time would be required in the examination of the application as filed. There is no basis to establish that a joint search of the Group I and II claims in a single application would be burdensome. Moreover, if the Restriction Requirement is made final, Applicants will be

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burdened with filing additional divisional applications, with the attendant application filing fees, to recapture restricted subject matter for which Applicants have already paid claim fees.

Applicants further elects for the method claims, with traverse Venezuelan Equine

Encephalitis Virus, and a boosting preparation of a single malarial antigen selected from recombinant non-alphavirus expression system: poxvirus expression system, and more specifically vaccinia.

However, a reasonable number of species may be claimed in a single application provided the application also includes an allowable claim generic to all the claimed species. CFR 1.141 and MPEP 806.04(a). The Alphavirus replicon, in the original claims, is generic to the species Venezuelan Equine Encephalitis Virus, Semliki Forest Virus and Sindbis virus. The poxvirus is generic to the species cowpox, k canarypox, vaccinia, modified vaccinia Ankara, and fowlpox. Therefore, the requirement for a restriction of species is improper.

In contrast, if the restriction is maintained, Applicants will need unnecessarily file multiple applications, and their associated fees, to cover the same discovery. This is an undue burden on Applicants with little or no burden on the USPTO. The same rational apply to the restrictions on malarial antigen, and boosting immunization preparation. The essence of this invention is a heterologous prime/boost regimen with a primary immunization using antigen expressed by an alphavirus replicon A search on immunization against malaria and prime/boost would be sufficient and not unnecessarily burdensome.

Therefore, the Restriction Requirement fails to establish the nature of the burden in a

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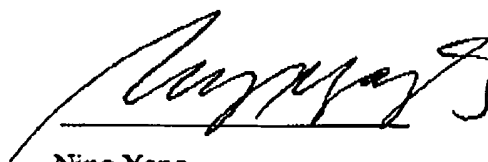
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search of the Group I and II claims and among species in a single application. Accordingly,

Applicants respectfully request the claims be rejoined for prosecution in this application.

Respectfully submitted,

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